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EXAMINER
RINES, ROBERT D

ART UNIT	PAPER NUMBER
3626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/783,648	HOLLAND ET AL.
	Examiner	Art Unit
	R. DAVID RINES	3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2004*.

2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All   b)☐ Some * c)☐ None of:

        1.☐ Certified copies of the priority documents have been received.

        2.☐ Certified copies of the priority documents have been received in Application No. _____.

        3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date *9/7/05*.

4) ☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____ .

DETAILED ACTION

Notice to Applicant

[1]   This communication is in response to the patent application filed2/20/08. It is noted that

this application benefits from Provisional Patent Application Serial Nos. 60/509404 and

60/527583 filed 10/7/03 and 12/5/03 respectively. The Information Disclosure Statement filed

9/7/05 been entered and considered. Claims 1-16 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in
> section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are
> such that the subject matter as a whole would have been obvious at the time the invention was made to a person
> having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the
> manner in which the invention was made.

[2]   Claims 1-2, 4-12, and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable

over Eggers et al. (United States Patent Application Publication #2006/0106649).

As per claim 1, Eggers et al. disclose method for downloading a drug library from a medication management unit to a medical infusion device having a primary memory and an existing drug library stored in the primary memory, comprising: determining that a drug library update needed event has occurred (Eggers et al.; paragraphs [0034] [0036] [0057] [0063] *see change location and new library); transmitting a new drug library from the medication management unit to the medical infusion device upon occurrence of the drug library update needed event (Eggers et al.; paragraphs [0034] [0057] *see location specific configuration database); storing the new drug library in a memory of the medical infusion device while maintaining the existing drug library in the primary memory (Eggers et al.; paragraphs [0057] [0070]); determining that a specific trigger event has occurred (Eggers et al.; paragraphs [0034] [0057]); and replacing the existing drug library in the primary memory with the new drug library upon occurrence of the trigger event (Eggers; paragraphs [0034] [0057]).

While Eggers et al. disclose storing the configuration and associated drug libraries in the memory of the infusion pump, Eggers et al. fail to specify storage in a cache memory. However, Examiner submits that it would have been obvious to use of the cache memory to store the drug library prior to storage in the bulk memory with the motivation of employing a well-known computer memory structure to facilitate a transfer of data.

As per claim 2, Eggers et al. disclose a method wherein the trigger event is selected from the group consisting of a completed infusion, a stopped infusion, a determination that the device is in a configurable mode, elapsed time, a specific date and time, creation of the new drug library, a download of a modified drug library to the medication management unit, and a determination that the existing drug library at the medical device needs updating (Eggers et al.; paragraphs [0034] [0057] [0063] see change configuration by location, patient, or updated library – NOTE: The selection of additional trigger events to constitute a user choice that is accommodated by the Eggers disclosure).

As per claim 4, Eggers et al. disclose a method wherein the drug library update needed event is selected from the group consisting of a completed infusion, a stopped infusion, elapsed time, a specific date and time, creation of the new drug library, a download of a modified drug library to the medication management unit, and a determination that the existing drug library at the medical device needs updating (Eggers et al.; paragraphs [0034] [0057] [0063] see change configuration by location, patient, or updated library.).

As per claim 5, Eggers et al. disclose a method wherein the step of determining when the trigger event has occurred is done by the medication management unit (Eggers et al.; paragraphs [0034] [0056] [0057] [0063] *see patient specific parameters).

As per claim 6, Eggers et al. disclose a method wherein the step of determining when the trigger event has occurred is done by the medical device (Eggers et al.; paragraphs [0034] [0056] [0057]

see location specific parameters).

As per claim 7, Eggers et al. disclose a method wherein the step of determining when the drug library update needed event has occurred is done by the medication management unit (Eggers et al.; paragraphs [0034] [0056] [0057] see location specific parameters).

As per claim 8, Eggers et al. disclose a method wherein the step of determining when the drug library update needed event has occurred is done by the medical device (Eggers et al.; paragraphs [0034] [0056] [0057] see location specific parameters).

NOTE: regarding claims 5-8, Examiner interprets the applied teachings of Eggers et al. to indicate that the type of trigger event dictates which networked device initiates the configuration change.

As per claim 9, Eggers et al. disclose a method further comprising the step of performing an infusion with the medical device using the existing drug library during the transmitting step (Eggers et al.; paragraphs [0034] [0051] [0057]).

As per claim 10, Eggers et al. disclose a method wherein the new drug library is stored in the cache memory while the medical device is performing an infusion (Eggers et al.; paragraphs [0034] [0051] [0057] [0070] see "multi-step").

As per claim 11, Eggers et al. disclose a medication management system for downloading a drug library from a medication management unit to a medical device having a primary memory and an existing drug library stored in the primary memory (Eggers et al.; paragraphs [0034] [0056] [0057]), comprising: a medication management unit having a processing unit and a storage medium coupled to the processing unit, the storage medium containing programming code executed by the processing unit (Eggers et al.; paragraph [0056] *see PDA) to: determine that a drug library update needed event has occurred (Eggers et al.; paragraphs [0034] [0056] [0057] *see location specific configuration), and transmit a new drug library from the medication management unit to a medical device upon occurrence of the drug library update needed event (Eggers et al.; paragraphs [0036] [0057] [0058]); and a medical device in electronic communication with the medication management unit, having a processor and a primary memory coupled to the processor, the primary memory containing an existing drug library and programming code executed by the processor (Eggers et al.; paragraphs [0034] [0057] *see medical device) to: store the new drug library in a memory of the medical device while maintaining the existing drug library in the primary memory (Eggers et al.; paragraphs [0057] [0070]), determine that a specific trigger event has occurred (Eggers et al.; paragraphs [0034] [0057]), and replace the existing drug library in the primary memory with the new drug library upon occurrence of the trigger event (Eggers; paragraphs [0034] [0057]).

While Eggers et al. disclose storing the configuration and associated drug libraries in the memory of the infusion pump, Eggers et al. fail to specify storage in a cache memory. However, Examiner submits that it would have been obvious to use of the cache memory to store the drug

library prior to storage in the bulk memory with the motivation of employing a well-known

computer memory structure to facilitate a transfer of data.

As per claim 12, Eggers et al. disclose a system wherein the trigger event is selected from the

group consisting of a completed infusion, a stopped infusion, a determination that the device is in

a configurable mode, elapsed time, a specific date and time, creation of the new drug library, a

download of a modified drug library to the medication management unit, and a determination

that the existing drug library at the medical device needs updating (Eggers et al.; paragraphs

[0034] [0057] [0063] see change configuration by location, patient, or updated library – NOTE:

The selection of additional trigger events to constitute a user choice that is accommodated by the

Eggers disclosure).

As per claim 14, Eggers et al. disclose a system wherein the drug library update needed event is

selected from the group consisting of a completed infusion, a stopped infusion, elapsed time, a

specific date and time, creation of the new drug library, a download of a modified drug library to

the medication management unit, and a determination that the existing drug library at the

medical device needs updating (Eggers et al.; paragraphs [0034] [0057] [0063] see change

configuration by location, patient, or updated library – NOTE: The selection of additional trigger

events to constitute a user choice that is accommodated by the Eggers disclosure).

As per claim 15, Eggers et al. disclose a system wherein the medical device is adapted to

perform an infusion using the existing drug library while the new drug library is transmitted

(Eggers et al.; paragraphs [0034] [0057] [0070]).

As per claim 16, Eggers et al. disclose a system wherein the new drug library is stored in the memory while the medical device is performing an infusion (Eggers et al.; paragraphs [0034] [0057] [0070]).

Regarding claims 12 and 14-16, the obviousness and motivation as discussed with regard to claim 11 above are applicable to claims 12 and 14-16 and are herein incorporated by reference.

[3]   Claims 3 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eggers et al. in view of Examiner's Official Notice.

As per claim 3 and 13, while Eggers et al. defines a number of operation modes (Eggers et al.; paragraphs [0031] [0041]), Eggers et al fail to specifically recited a power off or power on sleep mode.

However, Examiner takes Official Notice that it is well known in the art to include power on sleep and power off modes for networked electronic medical devices. One of ordinary skill in the art would have been motivated to employ commonly known device modes to maintain a number of different readiness states for the device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. DAVID RINES whose telephone number is (571)272-5585. The examiner can normally be reached on 8:30am - 5:00pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher L. Gilligan can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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6/23/08